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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,025	11/21/2003	Elliot Lorne Chaikof	133-02	3169

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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,025	CHAIKOF ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-76* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Election/Restrictions

3. Upon further consideration, the restriction requirement dated 20 June 2006 is hereby withdrawn and vacated. The claims will be restricted according to the instant Office action. Any inconvenience caused to Applicants is regrettable.

4. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods and products. The methods and agents/products rely upon synthetic protein copolymers of different structural variations but that have at the very minimum at least one hydrophilic block and at least one hydrophobic. However, the products ultimately differ in structure and the methods differ in modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Applicant is invited to clearly elect a single Group as it reads on a particular protein copolymer or method that uses said protein copolymer and to provide an appropriate claim that reads on the elected invention. The Groups set forth below appear to read on the claims as currently recited, but may be subject to further Restriction and/or species election depending on the claimed recitation.

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-11, 33, 34 and 37-40, drawn to a protein copolymer with two hydrophobic end blocks and a middle hydrophilic block, classified in class 530, subclass 353. Note, in claims 4-6, 9 and 10, Applicants are required to choose a single amino acid sequence for either the end block or middle block. When both are listed (e.g. in claim 6), Applicants must choose one sequence for each (e.g. one from SEQ ID No: 11/12 and one from SEQ ID No: 14/15/18). This is NOT an election of species.

II. Claims 12-17, 29 and 30, drawn to a film comprising the protein co-polymer of claim 2, classified in class 424, subclass 400.

III. Claim 18, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block in the form of a gel, classified in class 424, subclass 400.

IV. Claims 19, 20 and 31, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block in the form of a fiber or fiber network, classified in class 424, subclass 400.

V. Claims 21, 71 and 72, drawn to a method of generating a medical implant comprising using fiber networks, classified in class 424, subclass 423.

VI. Claims 22-25, 27 and 68-70, drawn to a method of for producing a plastic elastic protein copolymer by recombinant expression of said copolymer, classified in class 435, subclass 69.1. N.B. Applicant is required to elect

a single sequence from SEQ ID Nos: 45, 46, 47 or 48. This is **NOT** an election of species.

VII. Claim 26, drawn to a nucleic acid sequence comprising SEQ ID Nos: 45, 46, 47 or 48, classified in class 536, subclass 23.1. N.B. Applicant is required to elect a single sequence. This is **NOT** an election of species.

VIII. Claim 28, drawn to a medical device comprising a protein copolymer film, classified in class 424, subclass 423.

IX. Claim 28, drawn to a cell comprising a protein copolymer film, classified in class 424, subclass 422.

X. Claim 28, drawn to a tissue comprising a protein copolymer film, classified in class 424, subclass 422.

XI. Claim 28, drawn to an organ comprising a protein copolymer film, classified in class 424, subclass 422.

XII. Claim 32, drawn to a medical device at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 423.

XIII. Claim 32, drawn to a cell at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 423.

XIV. Claim 32, drawn to a tissue at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 423.

XV. Claim 32, drawn to an organ at least partially covered or reinforced with a protein copolymer fiber or fiber network, classified in class 424, subclass 423.

XVI. Claims 35 and 36, drawn to a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block in the form of a biocompatible coating on a device, classified in class 424, subclass 400.

XVII. Claim 41, drawn to a medical implant comprising a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 423.

XVIII. Claims 1 and 42, drawn to a drug delivery material comprising a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

XIX. Claim 43, drawn to a wound dressing comprising a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

XX. Claims 44 and 45, drawn to a cell that is completely or partially encapsulated by a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

XXI. Claim 44, drawn to a tissue that is completely or partially encapsulated by a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

XXII. Claim 44, drawn to an organ that is completely or partially encapsulated by a protein co-polymer with at least one hydrophilic block and at least one hydrophobic block, classified in class 424, subclass 400.

XXIII. Claims 46-56, drawn to a drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block which is cross-linked, classified in class 530, subclass 353.

XXIV. Claims 57-59, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block a functional binding site, classified in class 530, subclass 353.

XXV. Claim 61, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block comprising an adhesion molecule recognition site or enzyme active site, classified in class 530, subclass 353.

XXVI. Claims 62 and 63, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block further comprising an agent that is a drug or biologically active molecule, classified in class 530, subclass 353.

XXVII. Claims 64-66, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block further comprising an additional molecule, classified in class 530, subclass 353.

XXVIII. Claim 67, drawn to a protein copolymer with at least one hydrophilic block and at least one hydrophobic block further comprising a synthetic or

nature compound capable of effecting an alteration of a surface property of said copolymer, classified in class 530, subclass 353.

XXIX. Claim 73, drawn to a method of generating a wound dressing which is made of fiber copolymers, classified in class 424, subclass 445.

XXX. Claims 74 and 75, drawn to a method of generation a medical implant by using a film of Group II, classified in class 424, subclass 422.

XXXI. Claim 76, drawn to a method of generating a wound dressing which is made of a film of Group II, classified in class 424, subclass 445.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions I-III, V, VI and VII-XXVII are directed to related but patentably distinct products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are directed to patentably distinct products. While the commonality of each of the products is they contain protein copolymers with a at least one hydrophobic end block and at least one hydrophilic end block, each product is deemed to be unique and patentably distinct products. For instance, the products of copolymers that are made of films, gels or fiber networks require that the copolymers be made of the copolymers in such as way so as to produce unique structures which are both structural and functional non-equivalents because each has their own unique mechanical properties. Additionally, cells, tissues,

organs, wound dressings and medical implants which incorporate each of the copolymers in the form of gels, films or fibers are also patentably distinct products each possessing medical devices, cells, organs, tissues are also structurally and functionally unique and non-equivalents. Thus a search for a medical implant coated with a gel, a film or fiber would require three non-extensive searches; likewise a search for a medical implant coated with a film will not produce a co-extensive search for a cell encapsulated with the film. Finally, the groups are deemed not be obvious variants of one another, however, should Applicants dispute this assertion, then they are invited to inform the Examiner which Groups/claims Applicants deem as such.

7. Inventions VII and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06).

The DNA of group VII is related to the protein of group I by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, the DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of groups I and VII together would impose a serious search burden. In the instant case, the search of the polypeptides and the

polynucleotides are not coextensive. The inventions of Groups I and VII have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Finally, the proteins can be made by chemical synthesis and the DNA need not even be required for the production of the protein. As such, it would be burdensome to search the inventions of groups I and VII together.

8. Inventions VII and [II, III, V, VI and VII-XXVII] are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not related because the products use or require the protein which the DNA may encode. Structurally and functionally the protein and DNA are non-equivalent thus the DNA is not capable of being used in the products. Furthermore, there would be no coextensive search of the prior art which would place an undue search burden upon the examiner.

9. Inventions V, VI, XXIX, XXX and XXXI are directed to patentably distinct methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See

MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to methods of making wound dressings using a film copolymer (Group XXX), or a fiber network copolymer (Group XXIX) or methods of making medical implants using a film copolymer (Group XXX), or a fiber network copolymer (Group V), or methods of making a protein copolymer by recombinant techniques (Group VI). The methods are patentably distinct and separate because the method steps used in each method employs unique products, either DNA, films, or fiber networks, in order to make unique products. Thus the starting and end points are not convergent and method steps required to achieve the end point will differ in the use of structurally and functionally distinct products (film, fiber networks, DNA) in order to obtain structurally and functionally unique products (medical devices, would dressings or proteins) with unique mechanical properties. Thus, there would be no expectation that there would be co-extensive searches for any of the groups which would place an undue search burden upon the Examiner.

10. Inventions I and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the methods of making the protein copolymer can be achieved by chemical synthesis such as Fmoc chemistry. Thus the DNA is not required to make the product of Group I.

11. Inventions V/XXIX and IV are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the fiber network can be used in other material products such as in making biological sample containers coated with said fibers or fiber network.

12. Inventions XXX/XXXI and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the film can be used to make/coat biological sample containers with said film.

13. Inventions [V, VI, XXIX, XXX and XXXI] and [III, V, VI and VII-XXVII] are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not related because the products of Groups III, V, VI and VII-XXVII are not used in nor are they required in the methods of making for Groups [V, VI, XXIX, XXX and XXXI. Thus, there would be no coextensive searches which would induce a serious search burden for the Examiner.

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

NOTE: the requirement to elect a single amino acid sequence or single DNA sequence is NOT an election of species because each protein/DNA sequence is structurally and functionally unique wherein each different sequence requires its own unique search in the various amino acid or DNA databases. Thus the searches are not convergent and it would cause an undue search burden upon the Examiner and the USPTO resources.

Linking Claim

15. Claim 1 links inventions I, III, IV, XVI-XIX and XXIII-XXVIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking

claims, claim 39. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Potential Right to Rejoinder

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan M. Noakes
SMN
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